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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,635	08/09/2001	Nanna Kristensen Soni	4305/1H520US1	2913

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DARBY & DARBY P.C.
805 Third Avenue
New York, NY 10022

EXAMINER	
FOLEY, SHANON A	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,635	SONI ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-20,59,65 and 66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,4-16,18-20,59,65 and 66* is/are rejected.

7)☒ Claim(s) *17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Reconsideration

The request filed on 9/22/4 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/925635 is acceptable and a RCE has been established. An action on the RCE follows.

In the amendment submitted 9/22/4, applicant cancelled claims 1, 3, 21-57 and 60-64 and amended claims 2, 4-9, 11-20, 58, 59 and 65. Claims 2, 4-20, 58, 59, 65 and 66 are under consideration.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 4-8, 11-13, 16, 58, 59, and 66 remain rejected under 35 U.S.C. 102(e) as being anticipated by Gonczol et al. (US 6,448,389).

Applicant argues that the vaccine of Gonczol et al. does not contain an antigen since the reference only teaches a DNA encoding the gB antigen. Applicant states that claim 66 does not recite a DNA molecule either as an antigen itself or encoding a particular antigen.

Applicant's arguments have been fully considered, but are found unpersuasive. The vaccine of instant claim 66 requires (a) at least one immunogenic substance selected from antigens... and (b) an adjuvant comprising a salt formed with Mg. Gonczol et al. anticipate a

vaccine composition comprising (a) an immunogenic substance comprising cytomegalovirus DNA (an antigen) and (b) an adjuvant comprising magnesium hydroxide, see column 2, lines 22-27, column 4, line 63 to column 5, line 10 and column 6, lines 31-41. Gonczol et al. teach that the pΔRC-gB_{680}, pTet-gB and/or pΔRC-pp65 plasmids are "highly potent immunogens for HCMV", see column 4, lines 60-61, examples 8 and 14 and column 3, line 66 to column 5, line 10. Moreover, the instant specification defines cytomegalovirus DNA as a suitable antigen, see page 14, lines 18-20 and line 33 to page 15, line 18. Therefore, Gonczol et al. anticipate the antigen within the vaccine composition claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonczol et al. as applied to claims 2, 4-8, 11-13, 16, 58, 59, and 66 above, and further in view of Vogel et al. ("A Compendium of Vaccine Adjuvants and Excipients" in Vaccine Design: The Subunit and Adjuvant Approach (Chapter 7), M.F. Powell & M.J. Newmann, Eds. (Plenum Press, New York) 1995, pp. 141-228), supplied by applicant in the IDS of paper no. 5 for reasons of record.

Applicant argues that neither Gonczol et al. nor Vogel et al. anticipate a vaccine containing any of the antigens recited in claim 66. However, since the instant disclosure

encompasses CMV DNA as a suitable antigen, which is taught by Gonczol et al., the rejection is maintained for reasons of record.

Claims 2, 4-8, 11-13, 18, 58, 59 and 66 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Aviram et al. (US 6,362,236) and Conte et al. (US 5,464,633) as evidenced by Cruse et al. (Illustrated Dictionary of Immunology. Boca Raton: CRC Press; 1995, page 7.

Applicant asserts that "adjuvant", as used by Conte et al., implies an "additive" or an "ingredient", which is different from the immunological "adjuvant" of the instant invention. Applicant states that since Conte et al. do not define "adjuvant", applicant recites several excerpts from Conte et al. to extrapolate the definition of "adjuvant" used by Conte et al.

Applicant's arguments as well as a review of the reference have been fully considered, but are found unpersuasive. "Adjuvant" does not have multiple meanings. It is a substance that enhances the immune response to an antigen. Therefore, it would be an "additive" or an "ingredient" in an immunological composition. The standard definition of "adjuvant" is provided for applicant's convenience from Cruse et al. (Illustrated Dictionary of Immunology. Boca Raton: CRC Press; 1995, page 7. Since there is only one meaning for the term "adjuvant" and since Conte et al. do not apply the term out of context or incorrectly, it is clear that Conte et al. intends the term "adjuvant" by the only standard definition known.

In the first excerpt recited by applicant, the adjuvant referred to by Conte et al. is a particular class of adjuvant that works by a particular mechanism. In the second excerpt applicant refers to, Conte et al. are discussing various compression diluents that are traditionally applied to an external layer. Therefore, this is excerpt is not germane to a discussion of "adjuvants". Applicant also points to claim 9 of Conte et al., which mentions a certain type of

adjuvant known as hydrophobic diluents. However, this claim does not exclude or limit other adjuvants discussed in the entire disclosure of Conte et al. In the final excerpt recited by applicant, applicant asserts that titanium dioxide is referred to as an opacity agent, but "is also an example of an "adjuvant" or a pharmaceutical additive" (quoted from applicant's response on page 12, next to the last paragraph). On page 6, lines 17, Conte et al. recites, "and other adjuvants well known to the skilled artisan". Immediately preceding this phrase is "titanium dioxide". Therefore, it is maintained that Conte et al. specifically lists a specific example, titanium dioxide, followed by, "and other adjuvants" to clearly designate what the nature of the specific example, titanium dioxide, is. Therefore, it is clear that titanium dioxide has adjuvant properties and the ordinary artisan would have a reasonable expectation of success for using it in a vaccine composition.

Claims 14, 15 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonczol et al. as applied to claims 2, 4-8, 11-13, 16, 58, 59, and 66, or alternatively Aviram et al. and Conte et al. as applied to claims 2, 4-8, 11-13, 16, 58, 59, and 66 above for reasons of record.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gonczol et al. as applied to claims 2, 4-8, 11-13, 16, 58, 59, and 66 above, and further in view of Aviram et al. and Conte et al. for reasons of record.

Applicant traverses these rejections on the grounds that neither Gonczol et al. not Conte et al. teach the elements claimed for reasons discussed above. However, these arguments have not been found convincing. Therefore, the rejections are maintained for reasons of record.

Allowable Subject Matter

Claim 17 remains objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

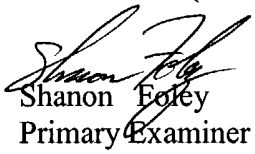
This is a continuation of applicant's earlier Application No. 09/925635. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Primary Examiner
Art Unit 1648